OCT - 4 2001

K013034

510(k) Premarket Notification Summary of Safety and Effectiveness Information	*ThermaCool IIA* September 7, 2001

Device Name: **ThermaCool IIA**
Common Name(s): RF Unit, coagulator
Classification Name: Electrosurgical cutting and coagulation device and accessories

Establishment Name & Registration Number:
Name: Thermage
Number: 2954746

Classification:
Title 21, Code of Federal Regulations,

§ 878.4400 Electrosurgical cutting and coagulation device and accessories. (a) Identification. An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current. (b) Classification. Class II.

ProCode: 79GEI

Equivalent Device(s):
The modified ThermaCool IIA claims substantial equivalence to the ***ThermaCool*** and ***ThermaCool II*** (K000944 & K003183).

Description of the Device:
The Thermage ThermaCool IIA device consists of the same four principal components as the ThermaCool and ThermaCool II as reviewed under the referenced earlier premarket notifications. The four principal components are:

- Thermage ThermaCool IIA RF Generator
- Thermage ThermaCool IIA Handpiece Connection Module
- Thermage ThermaCool IIA RF Cooling Module
- Thermage ThermaCool IIA RF Handpiece Assembly

The device generates radio frequency (RF) energy and operates in either monopolar or bipolar mode as selected by the user. The device continuously monitors output power, output energy, treatment duration, and measured impedance. When used in monopolar mode, a commercially available dispersive patient return electrode is utilized. When used in bipolar mode, the current returns via the handpiece insert tip and no dispersive electrode is needed. The handpiece attaches to the unit via an industry standard BNC type connector. As before, the intended use of the device is for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

The system has been modified and now includes a heating element and a new cryogen metering valve within the handpiece. The effect of the change is improving cryogen flow characteristics in the clinical setting.

Applicant / Sponsor Name / Address:
Thermage
4058 Point Eden Way
Hayward, CA 94545-3721
510.782.2286 telephone
510.782.2287 fax

Contact Person:
Pamela M. Buckman, R.N., M.S.
Thermage
4058 Point Eden Way
Hayward, CA 94545-3721
510.782.2286 telephone
510.782.2287 fax

Submission Correspondent:
Pamela M. Buckman, R.N., M.S.
Thermage
4058 Point Eden Way
Hayward, CA 94545-3721
510.782.2286 telephone
510.782.2287 fax

Manufacturing Facility:
At the present time, the ***ThermaCool IIA*** is contract manufactured according to Thermage specifications.

Performance Standards:
There are no applicable FDA mandated performance standards for electrosurgical cutting and coagulation device and accessories. However, voluntary standards such as in-house Standard Operating Procedures and QSR based vendor qualification procedures are in place and utilized in the production of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Ms. Pamela Buckman
Director, Regulatory and Clinical Affairs
Thermage, Inc.
4058 Point Eden Way
Hayward, California 94545-3721

Re: K013034
Trade/Device Name: ThermaCool IIA
Regulation Number: 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: September 7, 2001
Received: September 10, 2001

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walter, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K013034

DEVICE NAME : ThermaCool IIA

INDICATIONS FOR USE:

The ThermaCool IIA System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013034

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)